

**CONCEPT DHA - vitamin- mineral omega-3 supplement capsule, liquid filled**  
**US Pharmaceutical Corporation**

*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click [here](#).*

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**see all prescribing information for Concept DHA**

DESCRIPTION: Each capsule contains: Ferrous Fumarate (Elemental Iron) . . . . . 17.5 mg  
PolysaccharideIronComplex(ElementalIron).. 17.5mg  
(Equivalent to about 35 mg of elemental iron) Vitamin C (from ProAscorb C $\ddagger$ ) . . . . .  
. . . . . 25 mg FolicAcid..... 1mg ThiamineMononitrate(B1) ..... 2mg  
Riboflavin(B2) ..... 3mg Niacin (B3, from ProAscorb C $\ddagger$ ) . . . . .  
. . . . . 1.8 mg d-CalciumPantothenate(B5)..... 5mg PyridoxineHCl(B6) ..... 25mg Biotin (B7)  
..... 300 mcg Cyanocobalamin(B12) ..... 12.5mcg  
Copper(asCopperSulfate)..... 2mg  
Magnesium(asMagnesiumSulfate) . . . . . Zinc(asZincSulfate)..... Omega-3 Fatty Acids . .  
. . . . .  
(Derived from 310 mg Fish Oil) Docosahexaenoic Acid (DHA) . ..... Eicosapentaenoic Acid (EPA)  
. . . . . 5mg 10mg 200 mg156 mg 39 mg

Clinical Studies: Because Ferrous Fumarate is an organic complex, it contains no free ions, either ferric or ferrous. Polysaccharide Iron Complex is clinically non-toxic. Prior studies in rats demonstrated that Polysaccharide Iron Complex (PIC), administered as a single oral dose to Sprague Dawley rats did not produce evidence of toxicity at a dosage level of 5000 mg Iron/kg: (An Acute Oral Toxicity Study in Rats with Polysaccharide-Iron Complex. T.N.Merriman, M. Aikman and R.E. Rush, Springborn Laboratories, Inc. Spencerville, Ohio Study No. 3340.1 March - April 1994). Other clinical studies had demonstrated that Polysaccharide Iron gives a good hematopoietic response with an almost complete absence of the side effects usually associated with oral iron therapy. Picinni and Ricciotti suggested in 1982, that "the therapeutic effectiveness of Polysaccharide Iron Complex when compared with iron fumarate in the treatment of iron deficiency anemia, appears to be as active as the iron fumarate and as well tolerated, however, it exerted a greater influence on the level of hemoglobin and on the number of red cells..." and that, "it has been exceptionally well tolerated by all patients" (Picinni, L.-Ricciotti, M. 1982. Therapeutic effectiveness of an iron-polysaccharide complex in comparison with iron fumarate in the treatment of iron deficiency anemias): PANMINERVA MEDICA-EUROPA MEDICA, Vol. 24, No. 3, pp. 213-220 (July - September 1982). As mentioned above, the patented source of iron used in Concept DHATM (Ferrous Fumarate and Polysaccharide Iron Complex) provides a high level of elemental iron with a low incidence of gastric distress.

CONCLUSION: Based on the results of this study, the oral combination of Ferrous Fumarate and Polysaccharide Iron Complex was better tolerated and safer than the oral administration of Ferrous Fumarate alone. The conclusion of this research stated, that the addition of PIC to Ferrous Fumarate surprisingly allows the same concentration of Ferrous Fumarate to be better tolerated than the Ferrous Fumarate alone.

INDICATIONS: Concept DHATM is a prescription prenatal vitamin-mineral preparation containing omega-3 fatty acid supplements designed to supply nutritional supplementation for women throughout pregnancy and during the postnatal period to lactating and non-lactating mothers. Concept DHATM may also be used to improve the nutritional status of women before conception.

WARNING: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of reach of children. In case of accidental overdose, call a doctor or poison control center immediately. WARNING: Ingestion of more than 3 grams of omega-3 fatty acids from fish oils per day may have potential antithrombotic effects, including an increased bleeding time and INR (international normalized ratio). DHA should be avoided in patients with inherited

**PRECAUTIONS: General:** Folic acid in doses above 0.1 mg - 0.4 mg daily may obscure pernicious anemia, in that hematological remission can occur while neurological manifestations remain progressive.

**HOW SUPPLIED:** Concept DHATM are persimmon colored capsules imprinted "US" logo and "Concept DHA" in white. Child resistant bottles of 30 capsules NDC# 52747-621-30. Dispense in a tight, light-resistant container as defined in the USP/NF with a child resistant closure. Store at controlled room temperature 15 ° to 30 °C (59 ° to 86 ° F). Keep in a cool, dry place. Capsules are not USP.

**Supplement Facts**

Serving Size: 1 Capsule

	Amount Per Serving	%DV*
Ferrous Fumarate (anhydrous) (Equivalent to about 17.5 mg of Elemental Iron)	53.5 mg	41.7%
Polysaccharide Iron Complex (Equivalent to about 17.5 mg of Elemental Iron)	38 mg	** 19.4%
Vitamin C (from ProSorb C <sup>†</sup> )	25 mg	41.7%
Folic Acid	1 mg	250%
Thiamine Mononitrate (B <sub>1</sub> )	2 mg	133.3%
Riboflavin (B <sub>2</sub> )	3 mg	176.5%
Niacin (B <sub>3</sub> , from ProSorb C <sup>†</sup> )	1.8 mg	9%
d-Calcium Pantothenate (B <sub>5</sub> )	5 mg	50%
Pyridoxine HCl (B <sub>6</sub> )	25 mg	1250%
Biotin (B <sub>7</sub> )	300 mcg	100%
Cyanocobalamin (B <sub>12</sub> )	12.5 mcg	208.3%
Copper (as Copper Sulfate)	2 mg	100%
Magnesium (as Magnesium Sulfate)	5 mg	1.25%
Zinc (as Zinc Sulfate)	10 mg	66.7%
Omega-3 Fatty Acids	200 mg	
(Derived from 310 mg Fish Oil)		
Docosahexaenoic Acid (DHA)	156 mg	
Eicosapentaenoic Acid (EPA)	39 mg	

\* Percent of Daily Value    † Daily Value not established

Total Iron: Ferrous Fumarate + Polysaccharide Iron Complex

Inactive Ingredients: Hypromellose, Dextrawax, Titanium Dioxide, and FD&C Red 3.

NDC 52747-621-30

**Concept DHA™**

**PRESCRIPTION PRENATAL POSTNATAL  
VITAMIN MINERAL CAPSULES WITH  
OMEGA-3 FATTY ACIDS**

Store at controlled room temperature 15° to 30°C (59° to 86° F). Keep in a cool, dry place. Capsules are not USP.

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Marketed by: US Pharmaceutical Corporation  
Decatur, GA 30035, USA. Manufactured with Vcaps® capsule shells. Vcaps® and the Vcaps® Logo are trademarks used under license.

30 Capsules      † U.S. Patent No: 5,626,883

**INDICATIONS:** Concept DHA™ is a prenatal supplement containing omega-3 fatty acids designed to improve the nutritional status for women throughout pregnancy and during the postnatal period to lactating and non-lactating mothers. Concept DHA™ may also be used to improve the nutritional status of women before conception.

**DOSEAGE AND ADMINISTRATION:** Adults (persons over 12 years of age), one (1) capsule daily, orally, between meals, or as prescribed by a physician. Do not exceed recommended dosage. Do not administer to children under the age of 12. Consult package insert for full prescription information.

**CAUTION:** Rx only.      Rev. 07/2009    LC-1080



5274762130

## vitamin- mineral omega-3 supplement capsule, liquid filled

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:52747-621
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
FERROUS FUMARATE (UNII: R5L488RY0Q) (IRON - UNII:E1UOL152H7)		FERROUS FUMARATE	53.5 mg
IRON (UNII: E1UOL152H7) (IRON - UNII:E1UOL152H7)		IRON	38 mg
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)		ASCORBIC ACID	25 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)		FOLIC ACID	1 mg
THIAMINE MONONITRATE (UNII: 8K0I04919X) (THIAMINE - UNII:X66NSO3N35)		THIAMINE MONONITRATE	2 mg
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)		RIBOFLAVIN	3 mg
NIACIN (UNII: 2679MF687A) (NIACIN - UNII:2679MF687A)		NIACIN	1.8 mg
CALCIUM PANTOTHENATE (UNII: 568ET80C3D) (CALCIUM PANTOTHENATE - UNII:568ET80C3D)		CALCIUM PANTOTHENATE	5 mg

<b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1B16Z)	PYRIDOXINE HYDROCHLORIDE	25 mg
<b>BIOTIN</b> (UNII: 6SO6U10H04) (BIOTIN - UNII:6SO6U10H04)	BIOTIN	300 ug
<b>CYANOCOBALAMIN</b> (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	12.5 ug
<b>CUPRIC SULFATE</b> (UNII: LRX7AJ16DT) (COPPER - UNII:789U1901C5)	COPPER	2 mg
<b>MAGNESIUM SULFATE</b> (UNII: DE08037SAB) (MANGANESE - UNII:42Z2K6ZL8P)	MANGANESE	5 mg
<b>ZINC SULFATE</b> (UNII: 89DS0H96TB) (ZINC - UNII:J41CSQ7QDS)	ZINC	10 mg
<b>OMEGA-3-ACID ETHYL ESTERS</b> (UNII: D87YGH4Z0Q) (OMEGA-3-ACID ETHYL ESTERS - UNII:D87YGH4Z0Q)	OMEGA-3-ACID ETHYL ESTERS	200 mg

Product Characteristics

Color	pink (pink)	Score	score with uneven pieces
Shape	CAPSULE	Size	22mm
Flavor		Imprint Code	Concept;DHA;US
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52747-621-30	30 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		06/24/2009	

Labeler - US Pharmaceutical Corporation (048318224)